

<p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.</p> <p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(Use as many sheets as necessary)</i></p>				<p>Complete if Known</p> <table border="1"> <tr> <td>Application Number</td> <td>10/612,603</td> </tr> <tr> <td>Filing Date</td> <td>July 1, 2003</td> </tr> <tr> <td>First Named Inventor</td> <td>Chappey et al.</td> </tr> <tr> <td>Art Unit</td> <td>1648</td> </tr> <tr> <td>Examiner Name</td> <td>Humphrey, L.</td> </tr> <tr> <td>Attorney Docket Number</td> <td>57618-386029</td> </tr> </table>		Application Number	10/612,603	Filing Date	July 1, 2003	First Named Inventor	Chappey et al.	Art Unit	1648	Examiner Name	Humphrey, L.	Attorney Docket Number	57618-386029
Application Number	10/612,603																
Filing Date	July 1, 2003																
First Named Inventor	Chappey et al.																
Art Unit	1648																
Examiner Name	Humphrey, L.																
Attorney Docket Number	57618-386029																
Sheet	1	of	4														

Examiner Signature	/Louise Humphrey/	Date Considered	09/01/2010
-----------------------	-------------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of

4

Complete if Known

Application Number

10/612,603

Filing Date

July 1, 2003

First Named Inventor

Chappay et al.

Art Unit

1648

Examiner Name

Humphrey, L.

Attorney Docket Number

57618-386029

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/L.H./	5	ABRAVAYA, K. et al., "Detection of point mutations with a modified ligase chain reaction (Gap-LCR)," 1995, Nucl. Acids Res., 23:675-682	
/L.H./	6	ALLAIN, J.-P. et al., "Long-Term Evaluation of HIV Antigen and Antibodies to p24 and gp41 in Patients with Hemophilia," 1987, N. Engl. J. Med., 317:1114-1121	
/L.H./	7	ALTSCHUL, S. et al., "Basic Local Alignment Search Tool," 1990, J. Mol. Biol. 215:403-410	
/L.H./	8	ALTSCHUL, S. et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," 1997, Nucleic Acids Res., 25:3389-3402	
/L.H./	9	BARANY, F., "Genetic disease detection and DNA amplification using cloned thermostable ligase," 1991, Proc. Natl. Acad. Sci. USA, 88:189-193	
/L.H./	10	BARRE-SINOUESS, F. et al., "Isolation of a T-Lymphotropic Retrovirus from a Patein at Risk for Acquired Immune Deficiency Syndrome (AIDS)," 1983, Science, 220:868-871	
/L.H./	11	COLONNO, R. et al., "Identification of 150L as the Signature Atazanavir (ATV)-Resistance Mutation in Treatment-Naïve HIV-1-Infected Patients Receiving ATV-Containing Regimens," The Journal of Infectious Diseases, May 15, 2004; 189:1802-10	
/L.H./	12	COTTON, R. et al., "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations," 1988, Proc. Natl. Acad. Sci. USA, 85:4397-4401	
/L.H./	13	Current Protocols in Molecular Biology, Ausubel, F.M. et al. eds., John Wiley & Sons, NY, 2010 Table of Contents and list of yearly supplements	
/L.H./	14	FAHAM, M. and COX, D., "A Novel In Vivo Method to Detect DNA Sequence Variation," 1995, Genome Res., 5:474-482	
/L.H./	15	FISCHER, S. and LERMAN, L., "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: Correspondence with melting theory," 1983, Proc. Natl. Acad. Sci. USA, 80:1579-83	
/L.H./	16	FREEDMAN, D., PISANI, R., and PURVES, R., 1980, Statistics, W.W. Norton, New York	
/L.H./	17	GOEDERT, J. et al., "Effect to T4 Count and Cofactors on the Incidence of AIDS in Homosexual Men Infected With Human Immunodeficiency Virus," 1987, JAMA, 257:331-334	
/L.H./	18	GUPTA, S. et al., "Combinations of Mutations in the Connection Domain of Human Immunodeficiency Virus Type 1 Reverse Transcriptase: Assessing the Impact of Nucleoside and Nonnucleoside Reverse Transcriptase Inhibitor Resistance," May 2010, American Society for Microbiology, Vol. 54, No. 5, p. 1973-1980	
/L.H./	19	HIRSCH, M. et al., "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection: 2008 Recommendations of an International AIDS Society-USA Panel," July 15, 2008, Clinical Infectious Diseases, 47:266-85	
/L.H./	20	KAN, Y. and DOZY, A., "Antenatal Diagnosis of Sickle-Cell Anaemia by D.N.A. Analysis of Amniotic-Fluid Cells," 1987, The Lancet, 2:910-912	

Examiner Signature	/Louise Humphrey/	Date Considered	09/01/2010
--------------------	-------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		<i>Application Number</i>		10/612,603	
		<i>Filing Date</i>		July 1, 2003	
		<i>First Named Inventor</i>		Chappay et al.	
		<i>Art Unit</i>		1648	
		<i>Examiner Name</i>		Humphrey, L.	
Sheet	3	of	4	<i>Attorney Docket Number</i>	
57618-386029					

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
/L.H./	21	KARLIN, S. and ALTSCHUL, S., "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," 1990, Proc. Natl. Acad. Sci. USA, 87:2264-2268		
/L.H./	22	KARLIN, S. and ALTSCHUL, S., "Applications and statistics for multiple high-scoring segments in molecular sequences," 1993, Proc. Natl. Acad. Sci. USA, 90:5873-5877		
/L.H./	23	KELLAM, P. and LARDER, B., "Recombinant Virus Assay: a Rapid, Phenotypic Assay for Assessment of Drug Susceptibility of Human Immunodeficiency Virus Type 1 Isolates," 1994, Antimicrobial Agents and Chemo., 38:23-30		
/L.H./	24	LANDEGRENN, U. et al., "A Ligase-Mediated Gene Detection Technique," 1988, Science, 241:1077-1080		
/L.H./	25	LUCAS, S. "The pathology of HIV infection," 2002, Lepr. Rev., 73:64-71		
/L.H./	26	MAXAM, A. and GILBERT, W., "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," 1980, Methods in Enzymology, 65:499-560		
/L.H./	27	MESSING, J. et al., "A system for shotgun DNA sequencing," 1981, Nuc. Acids Res., 9:309-321		
/L.H./	28	MYERS, R. et al., "Detection of Single Base Substitutions by Ribonuclease Cleavage at Mismatches in RNA:DNA Duplexes," 1985, Science, 230:1242-1246		
/L.H./	29	NIKIFOROV, T. et al., "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms," 1994, Nucl. Acids Res., 22:4167-4175		
/L.H./	30	NORRIS, T., "HIV Update," 2002, Radiol. Technol., 73:339-363		
/L.H./	31	ORITA, M. et al., "Rapid and Sensitive Detection of Point Mutations and DNA Polymorphisms Using the Polymerase Chain Reaction," 1989, Genomics, 5:874-879		
/L.H./	32	ORITA, M. et al., "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms," 1989, Proc. Natl. Acad. Sci. USA, 86:2766-2770		
/L.H./	33	ORUM, H. et al., "Single base pair mutation analysis by PNA directed PCR clamping," 1993, Nucl. Acids Res., 21:5332-5336		
/L.H./	34	PCR Strategies, 1995, Innis et al. eds., Academic Press, Inc.		
/L.H./	35	PEARSON, W. and LIPMAN, D., "Improved tools for biological sequence comparison," 1988, Proc. Natl. Acad. Sci. USA, 85:2444-2448		

Examiner Signature	/Louise Humphrey/	Date Considered	09/01/2010
--------------------	-------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/612,603
(Use as many sheets as necessary)				Filing Date	July 1, 2003
				First Named Inventor	Chappay et al.
				Art Unit	1648
				Examiner Name	Humphrey, L.
Sheet	4	of	4	Attorney Docket Number	57618-386029

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
/L.H./	36	PIATAK, M. et al., "High Levels of HIV-1 in Plasma During All Stages of Infection Determined by Competitive PCR," 1983, Science, 259:1749-1754		
/L.H./	37	POPOVIC, M. et al., "Detection, Isolation, and Continuous Production of cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS," 1984, Science, 224:497-500		
/L.H./	38	RICHMAN, D., "Resistance, Drug Failure, and Disease Progression," 1994, AIDS Research Hum. Retroviruses 10:901-905		
/L.H./	39	RUSSELL, W. et al., "Specific-locus test shows ethylnitrosourea to be the most potent mutagen in the mouse," 1979, Proc. Natl. Acad. Sci. USA, 76:5818-5819		
/L.H./	40	SAMBROOK et al., 2001, Molecular Cloning : A Laboratory Manual, Cold Spring Harbor Laboratory, 3rd ed., NY		
/L.H./	41	SANGER, F. et al., "DNA sequencing with chain-terminating inhibitors," 1977, Proc. Natl. Acad. Sci USA, 74:5463-5467		
/L.H./	42	SOUTHERN, E.M., "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," 1975, J. Mol. Biol., 98:503-517		
/L.H./	43	SYVANEN, C. et al., "A Primer-Guided Nucleotide Incorporation Assay in the Genotyping of Apolipoprotein E," 1990, Genomics, 8:684-692		
/L.H./	44	THIEDE, C. et al., "Simple and sensitive detection of mutations in the ras proto-oncogenes using PNA-mediated PCR clamping," 1996, Nucl. Acids Res., 24:983-984		
/L.H./	45	TORELLI, A. and ROBOTTI, C., "ADVANCED and ADAM: two algorithms for the analysis of global similarity between homologous informational sequences," 1994, Comput. Appl. Biosci., 10:3-5		
/L.H./	46	URDEA, M., "Synthesis and Characterization of Branched DNA (bDNA) for the Direct and Quantitative Detection of CNV, HBV, HCV, and HIV," 1993, Clin. Chem., 39:725-726		
/L.H./	47	WAGNER, R. et al., "Mutation detection using immobilized mismatch binding protein (MutS)," 1995, Nucl. Acids Res., 23:3944-3948		
/L.H./	48	WHITCOMB, J. et al., "Broad Nucleoside Reverse-Transcriptase Inhibitor Cross-Resistance in Human Immunodeficiency Virus Type 1 Clinical Isolates," 2003, J. Infectious Diseases, 188:992-1000		
/L.H./	49	YOUIL, R. et al., "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII," 1995, Proc. Natl. Acad. Sci USA, 92:87-91		

Examiner Signature	/Louise Humphrey/	Date Considered	09/01/2010
--------------------	-------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.